Page 2 Serial No. 10/773,604 Response to Official Action

In the Claims:

- 1. (currently amended) A prosthesis for implant in a human patient body containing a rupture indicator comprising:
- (a) an at least one elastomeric external envelope; of medical grade elastomer containing a fluid material and a biologically compatible chemical indicator for indicating rupture of said prosthesis, and
- (b) an internal envelope of medical grade elastomer disposed within said external envelope, said internal envelope containing an implant <u>a</u> filling material contained in the elastomeric envelope; and

a biologically compatible rupture indicator contained within the elastomeric envelope capable of leaking out of the envelope and causing a body change detectable to the patient.

- 2. (currently amended) The prosthesis containing a rupture indicator of Cclaim 1, wherein said biologically compatible chemical the rupture indicator is a at least one dye.
- 3. (currently amended) The prosthesis containing a rupture indicator of Cclaim 2, wherein said biologically compatible chemical the rupture indicator is methylene blue.
- 4. (currently amended) The prosthesis containing a rupture indicator of Colaim 2, wherein said biologically compatible chemical indicator the rupture indicator is at least ene-selected from the group consisting of aurintricarboxylic acid (ATA), halogenated ATA, sulfonated ATA, sulfonated-halogenated ATA, phosphorylated ATA, anazolene sodium, eosine I bluish, eosine yellowish, erythrosine, Evan's blue (EB), fast green FCF, fuchin(e) acid, iodophthalein sodium, rose bengal, sulfobromophthalein sodium, suramin sodium, trypan blue, trypan red, rosaniline chloride, crystal violet, methyl blue, methyl green, coomassie blue, basic fuchsin, malachite green, brilliant green, aniline blue, brilliant cresyl blue, safranin O, ethyl violet, pararosaniline acetate, methyl violet, direct yellow, direct red, ponceau S, ponceau SS, nitrosulfonazo III, chicago sky blue 6B,

Page 3 Serial No. 10/773,604 Response to Official Action

calcion or RG-13577, FD&C red No. 3, FD&C red No. 40, FD&C blue No. 1, and FD&C yellow No. 5, and combinations of these.

- 5. (currently amended) The prosthesis containing a rupture indicator of Cclaim 1, wherein said biological compatible chemical the rupture indicator is an odour generating agent which generates a smell as the body change detectable to the patient when leaking out from said the prosthesis.
- 6. (currently amended) The prosthesis containing a rupture indicator of Cclaim 1, wherein said biological compatible chemical the rupture indicator is a sensation agent which causes a local sensation as the body change detectable to the patient when leaking out from said the prosthesis.
- 7. (currently amended) The prosthesis containing a rupture indicator of Cclaim 1, wherein said the prosthesis is a breast prosthesis.
- 8. (currently amended) The prosthesis containing a rupture indicator of Cclaim 1, wherein said the prosthesis is at least one implanted in a portion of the body selected from the group consisting of brow, nose, cheek, chin, lips, pectoral, triceps, and biceps, genitals, buttocks, and calf prostheses.
- 9. (currently amended) The prosthesis containing a rupture indicator of Cclaim 1, wherein said external lumen further comprises a filling means valve disposed in the elastomeric envelope for filling said fluid material adding or removing rupture indicator to or from the prosthesis.
- 10. (currently amended) The cosmetic and reconstructive prosthesis containing a rupture indicator of Cclaim 9, wherein said filling means the valve is a self-sealing valve.

Page 4

Serial No. 10/773,604

Response to Official Action

- 11. (currently amended) A method of detecting rupture of a cosmetic and reconstructive prosthesis in a human patient body, comprising:
- (a) surgically implanting a prosthesis centaining a biologically compatible chemical indicator having at least one elastomeric envelope and a filling material contained therein for indicating rupture of said prosthesis in a location of athe patient body in need of said prosthesis; and

adding into the prosthesis a biologically compatible rupture indicator, capable of leaking out of the envelope and causing a body change detectable to the patient; and

- (b)detecting the body change caused by the rupture a change of a body secretion or peripheral blood for indication of leaking out of said indicator upon leaking out from said the prosthesis.
- 12. (currently amended) The method of Cclaim 11, wherein the body change detectable to the patient is a change in a said-body secretion-is at least one selected from the group consisting of urine, saliva, perspiration and feces, and combinations of these.
- 13. (currently amended) The method of Cclaim 12 11, wherein said change the body change detectable to the patient is a presence of said chemical the indicator or a metabolized product thereof in said at least one body secretion or peripheral blood.
- 14. (currently amended) The method of Cclaim 12, wherein said the change is an odour from said indicator in said emanating from the body secretion.
- 15. (currently amended) The method of <u>Gclaim 12</u>, wherein said the change is a color change of at least one of said body secretion.

Page 5

Serial No. 10/773,604

Response to Official Action

16. (currently amended) The method of <u>claim 11</u>, <u>wherein the body change detectable</u> to the patient is <u>detecting rupture of a cosmetic and reconstructive prosthesis</u> comprising:

(a) surgically implanting a prosthesis containing a biologically compatible chemical indicator for indicating rupture of said prosthesis in a location of a patient body in need of said prosthesis; and

(b) detecting a change locally to a portion of the body around said the prosthesis for indication of leaking out of said indicator from said prosthesis.

17. (currently amended) The method of Colaim 16, wherein said change the body change detectable to the patient is a local skin color change.

18. (currently amended) The method of Colaim 16, wherein said change the body change detectable to the patient is a local sensation.

19. (cancelled)

Please add the following claims:

20. (new) The prosthesis of claim 1, further comprising two elastomeric envelopes, a first elastomeric envelope containing the filling material and a second elastomeric envelope containing the rupture indicator.

21. (new) The prosthesis of claim 20, wherein the second envelope is external to the first envelope, and wherein upon rupture of the exterior envelope the rupture indicator leaks out and causes a body change detectable to the patient, alerting the patient of rupture of the external envelope and impending rupture of the first internal envelope and the filling material contained therein.

Page 6 Serial No. 10/773,604 Response to Official Action

- 22. (new) The method of claim 11, wherein the prosthesis further comprises two elastomeric envelopes, first elastomeric envelope containing the filling material and a second elastomeric envelope containing the rupture indicator.
- 23. (new) The method of claim 22, wherein the second envelope is external to the first, and wherein upon rupture of the exterior envelope the rupture indicator leaks out and causes a body change detectable to the patient, alerting the patient of rupture of the external envelope and impending rupture of the first internal envelope and the filling material contained therein.
- 24. (new) A method of detecting impending rupture of a prosthesis in a human patient body, comprising:

implanting in a location of the body a prosthesis having two elastomeric envelopes, a first elastomeric envelope containing the filling material and a second elastomeric envelope external to the first envelope;

adding within the external envelope a biologically compatible rupture indicator, capable of leaking out and causing a body change detectable to the patient upon rupture of the second external envelope; and

detecting the body change caused by the rupture indicator upon leaking out from the external envelope prior to rupture of the first internal envelope.